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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,767	12/27/2001	Yoshu Yoshioka	NITT.0051	9780
38327	7590	09/13/2004	EXAMINER	
REED SMITH LLP 3110 FAIRVIEW PARK DRIVE, SUITE 1400 FALLS CHURCH, VA 22042			MEHTA, ASHWIN D	
		ART UNIT	PAPER NUMBER	
		1638		

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	10/026,767	Applicant(s)	YOSHIBA ET AL.
Examiner	Ashwin Mehta	Art Unit	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 24 June 2004.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 4-9,13-15,26-31 and 34-39 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 4-9,13-15,26-31 and 34-39 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 December 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6032004 & 6242004.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objections to claims 2-6, 10-12, 16-23 are withdrawn, in light of the claim cancellations or amendments.
3. The rejection of claims 1, 10, 11, and 12 under 35 U.S.C. 101 is withdrawn, in light of the claim cancellations.
4. The rejections of claims 1, 9-12, and 21-33, and 39 under 35 U.S.C. 112, second paragraph, are withdrawn in light of the claim amendments or cancellations.
5. The rejection of claims 3, 6, and 17 under 35 U.S.C. 102(b) is withdrawn, in light of the claim cancellations or amendments.
6. The rejections of claims 1-3, 10-12, 16-25, and 32-33 under 35 U.S.C. 103(a) are withdrawn, in light of the claim cancellations.

*Information Disclosure Statement*

7. The citation for Y., Igarashi et al. in the IDS submitted June 24, 2004 is lined through because it does not recite the date of publication. See 37 CFR 1.98. The date is not printed on the reference itself, either. The date of publication should include the month and day if the reference was published in the year before the priority date.

***Claim Rejections - 35 USC § 112***

8. Claims 7, 15, and 34-39 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed March 24, 2004. Applicants traverse the rejection in the paper filed June 24, 2004. Applicants' arguments were fully considered but were not found persuasive.

Regarding the rejection of claim 7 for the recitation, "introducing said vector according to claim 6 into calli derived from a rice plant to grow said calli": Applicants argue, in relation to all of the rejections under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, that the claims have been amended (response, page 6, 5<sup>th</sup> full paragraph). However, the amendment to claim 7 does not address this rejection. It remains unclear what is meant by growing calli by introducing a vector into it. It is suggested that claim 7 be amended by 1) replacing the recitation, "to grow" in line 2 with --, growing--, or 2) deleting the recitation, "to grow said calli" in line 2.

Regarding the rejection of claims 34-39 for the recitation, "said seed having been collected from said rice": the claim amendments do not address this rejection. It is suggested that the claims 34 and 35 be amended by adding, at the end, the recitation, --, wherein said seed comprises said introduced rice or Arabidopsis P5CS gene and said antisense ProDH gene--, and

that claims 36-39 be amended by adding, at the end, the recitation, --, wherein said seed comprises said vector--.

Regarding the rejection of claim 15: the claim was rejected because it is unclear what is being crossed with the “rice plant obtained by introducing said vector according to claim 6 by genetic engineering”. The claim amendments do not address this part of the rejection. It is suggested that the recitation, --a rice plant-- be inserted in line 2 after “crossing”.

***Claim Rejections - 35 USC § 112***

9. Claims 4-9, 13-15, 26-31, and 34-39 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention), for the reasons of record stated in the Office action mailed March 24, 2004.

Applicants traverse the rejection in the paper filed June 24, 2004. Applicants’ arguments were fully considered but were not found persuasive.

Applicants argue that it was known in the art to make transgenic plants more tolerant to freezing and high salinity by transformation with an antisense ProDH gene (response, page 7, 1<sup>st</sup> full paragraph). However, the claims encompass the introduction of both the antisense ProDH gene and a P5CS gene in sense orientation. Applicants also argue that proline accumulation may be toxic to plants depending on the type of plant, and cite a publication indicating the survival ratio of rice plants is increased with a proper amount of proline, that the survival ratio of rice plants with 10 to 100 mM Pro treatment, taught in the reference, increased from 0 to 90%, and

that proline concentrations of 500 mM decreased survival ratio (response, page 7, 1<sup>st</sup> full paragraph). However, the specification does not teach the concentration of proline in transgenic plants comprising the claimed constructs. The specification indicates that proline accumulated 100 times or more in transgenic plants compared to controls, but it fails to indicate that the amount of proline accumulated in the plants comprising the claimed constructs was toxic to the plant. This is questioned as the specification does not indicate how the results shown in Figure 3 relate to transgenic rice plants containing the claimed constructs. That is, while the specification indicates on page 19 that the claimed plants were among the transgenic rice plants tested, Figure 3 does not show the results for the claimed plants themselves, but only ambiguously presents the survival of "Transgenic" plants. There is no indication that the claimed transgenic plants, rather than the other transgenic plants comprising the other constructs discussed in the specification, actually showed the survival rates shown in Figure 3. As the claimed transgenic plants have been made and tested, it is suggested that Applicants submit a declaration under 37 CFR 1.132 indicating the survival rates of the claimed transgenic plants, made and tested as taught in the specification.

***Claim Rejections - 35 USC § 103***

10. Claims 4-9, 13-15, 26-31, and 34-39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu et al. (Plant Sci. 1998, Vol. 139, pages 41-48) in view of Igarashi et al. (Plant Mol. Biol., 1997, Vol. 33, pages 857-865), Yoshiba et al. (Plant J., 1995, Vol. 7, pages 751-760), Rashid et al. (Plant Cell Rep., 1996, Vol. 15, pages 727-730), Shimamoto et al. (Nature, 1989, Vol. 338, pages 274-276), and Nanjo et al. (FEBS Lett., 1999, Vol. 461, pages

205-21), for the reasons of record stated in the Office action mailed March 24, 2004. Applicants traverse the rejection in the paper filed June 24, 2004. Applicants' arguments were fully considered but were not found persuasive.

Applicants argue that each reference is limited to introducing just one of P5CS gene and antisense gene of ProDH in a rice plant, not both (response, page 9, 1<sup>st</sup> full paragraph). However, Applicants are arguing against the references individually. One cannot show nonobviousness by arguing against the references individually when the rejection is based on a combination of references. See *In re Keller*, 642 F.2d, 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co., Inc.*, 800 F.2d, 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants argue that the constructs of the invention serve the unique purpose of increasing proline accumulation 100 times or more, as supposedly summarized by the Examiner in the last Office action on page 7. Applicants argue throughout their remarks that the invention introduces the specific combination of the P5CS gene and antisense ProDH gene into rice plants to serve the unique purpose of increasing proline accumulation 100 times or more (response, page 9, 1<sup>st</sup> full paragraph to page 10, 3<sup>rd</sup> full paragraph). However, none of the claims make any mention of the proline content of the transgenic plants. Applicants' arguments therefore are not commensurate with the scope of the claims. See *In re Grasselli*, 713 F.2d 731, 741, 218 USPQ 769, 777 (Fed. Cir. 1983). Regarding Applicants' citation of page 7 of the last Office action: the action states the specification indicates that proline content accumulated to a higher extent in transgenic plants comprising a P5CS cDNA in sense orientation and the antisense ProDH cDNA. However, the Office action does not indicate or summarize that the specification teaches that the claimed construct was made for the specific intent of increasing proline content in transgenic plants

specifically 100 times or more. Further, the specification does not teach that the combination of the P5CS cDNA in sense orientation and ProDH cDNA in antisense orientation was made for the purpose of increasing proline accumulation specifically 100 times or more in transgenic plants, as implied in Applicants' arguments. The specification does not teach that the claimed transgenic plants that accumulated proline less than 100 times or more failed to increase stress tolerance. Applicants argue that the advantages of the construct of the invention does not flow from the cited references, since they fail to suggest introducing both P5CS and antisense ProDH in a rice plant (response, page 10, 1<sup>st</sup> full paragraph). However, it is not necessary that a reference actually suggest changes or possible improvements that Applicant made. See *In re Scheckler*, 438 F.2d 999, 1001; 168 USPQ 716, 717 (CCPA 1971). The ordinarily skilled artisan is presumed to know more about the art than only what is disclosed in the applied references, and has knowledge apart from the content of the references. *In re Bode*, 550 F.2d 656, 660, 193 USPQ 12, 16 (CCPA 1977); *In re Jacoby*, 309 F.2d 513, 516, 135 USPQ 317, 319 (CCPA 1962). Conclusions of obviousness can then be drawn "from common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. *In re Bozek*, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969). The references do teach that proline content did accumulate in the transgenic plants expressing a P5CS gene and in transgenic plants expressing a ProDH antisense gene, and that the transgenic plants showed increase tolerance to freezing, water, or salt stress. Given these teachings, one of ordinary skill in the art would have had a reasonable expectation of success at increasing freezing, water, and salt stress tolerance in transgenic rice plants transformed with both a P5CS gene in sense orientation and a ProDH gene in antisense orientation and that proline content

would be increased in those plants. Applicants also argued that the “connection locations” on the construct of Figure 1D served the unique purpose of increasing proline content 100 times or more in transgenic rice plants transformed with that construct (response, page 9, 1<sup>st</sup> full paragraph). However, the specification does not present any such surprising results showing that the particular locations of the genes in the transforming vector affected the results in any manner.

***Summary***

11. Claims 4-9, 13-15, 26-31, and 34-39 remain rejected.
12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Contact Information***

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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September 9, 2004



Ashwin D. Mehta, Ph.D.  
Primary Examiner  
Art Unit 1638